

Organization: Gulf War Steering Committee
Date: April 20, 2011

Minutes

Attendees:

Committee Members:

L. Maximilian Buja, MD
David Christiani, MD (teleconference)
Tilo Grosser, MD
Anthony Hardie
Robert P. Kelch, MD
James P. O'Callaghan, PhD
Robert Wenzel, MD
Roberta White, PhD

ORD Attendees:

Joel Kupersmith, MD
Timothy O'Leary, MD, PhD
William Goldberg, PhD
Robert Jaeger, PhD
Holly Birdsall, MD, PhD
Cheylynne Bosley

Guest Attendees:

VA Office of Public Health and Environmental Hazards
Terry Walters, MD, MPH
Michael Peterson, PhD, MPH, DVM
Aaron Schneiderman, PhD. MPH
Special Assistant to the Secretary
Col. Jeff Peters
Congressional Directed medical Research Program (CDMRP)
LCDR Mark Clayton, PhD
Melissa Forsythe, PhD (RET. Col)

Minutes:

- 1) Dr. Kupersmith gave a brief overview on expectations of the Gulf War Steering Committee.
 - a. There are two things people are wanting from the Gulf War Steering Committee:
 1. More interaction among researchers
 2. Strategic plan for moving forward
 - i. Dr. Birdsall will later discuss the research information management system

- ii. Dr. O'Leary will speak about Million Veterans Program (MVP)
 - b. There needs to be more interaction with the CDMRP group in the future to further advance research.
 - c. A question raised by Dr. White concerning available resources. The response was that Research and Development is expecting budget cuts and then a flat budget for the foreseeable future. ORD will continue, however, to target for \$15 million dollars for Gulf War Research.
- 2) Dr. Jaeger, the Acting Director of the Deployment Health Research Program, discussed the Deployment Health Research Program and his new position within the Office of Research and Development (ORD). The Deployment Health Research program has posted an announcement for a Director of Gulf War Exposure Research.
- 3) Overview of the Million Veteran Program (MVP) and Genomic Medicine Program given by Dr. O'Leary.
 - a. The Genomic program includes numerous programs, including the MVP protocol. A few reasons that the programs were developed include:
 - i. Many forms of military exposure have a genetic component (established by research done on the Twins PTSD study).
 - ii. It complements the health system as a whole.
 - iii. It provides a different approach to looking at Veterans problems.
 - b. MVP is one of VA's transformation initiatives.
 - c. For MVP: There are 26 sites running (as of the day of the meeting). Currently the data system and call center are operational and are centralizing recruitment. There are additional sites (VA Medical Centers) asking to join the program. The target is to have 1 million Veterans enrolled in 7 years. Work on the program is on-going in program education and communications.
 - d. It was made clear that whereas MVP is recruiting only users of the VA healthcare system, the new National Gulf War Cohort that is being developed within CSP which will recruit both users and non-users.
 - e. Additional information discussed about MVP included:
 - i. There is a plan for on-going contact with Veterans.
 - ii. The program was designed with input from many Veteran focus groups and there was a close cooperation with VSOs from the beginning.
 - iii. Samples are coded and everything is shipped to one location (Boston).
 - iv. Investigators wishing to access samples, information, etc. must be behind the VA firewall, meaning non-VA investigators must partner with a VA investigator.
- 4) Presentation by Drs. Peterson and Walters from the Office of Public Health and Environmental Hazards
 - a. Historical Overview of OPHEH efforts and findings on the 1991 Gulf War
 - 1. Mortality Studies Results
 - 2. Motor Vehicle Accidents
 - 3. National Health Survey Phase I and II

- b. Overview of OPHEH Current and Proposed Studies of 1991 Gulf War
 - 1. Gulf War Neurological Mortality Study II
 - 2. Gulf War Follow-Up Study 2010 (Questionnaires)
 - c. Other Studies
 - 1. National Health Study for OEF/OIF Veterans
 - i. Healthcare utilization
 - ii. Chronic Medical Conditions
 - 2. Military Working Dogs
 - 3. Collaborations with CDC
- 5) Presentation by Dr. Birdsall on ORD's Research Information Management System.
- a. ORD is developing a way to track all of their studies (working with Colexis)
 - b. It is being customized for VA ORD and it will have a specific search for Gulf War Illness related studies
 - c. Will allow ORD to check for duplicate funding with National Institute of Health's studies
 - d. It will provide a "footprint" of our program
 - e. It will be publically accessible (similar to NIH)
- 6) Presentation by Dr. Forsythe (RET. Col) from the Congressionally Directed Medical Research Program (CDMRP), Gulf War Illness Research Program (GWIRP).
- a. CDMRP partnerships (funded as add-ons from advocates)
 - b. Scope of CDMRP Funds and Awards: \$8 million in FY10 and in FY11 for the Gulf War Illness Research Program
 - c. CDMRP reviewed its Gulf War funding history and its current portfolio
 - d. CDMRP Gulf War clinical and basic science studies listed – 4 award mechanisms available in FY10
 - e. FY11 Priority areas presented
- 7) Discussion about the draft Strategic Plan lead by Dr. Goldberg
- a. Currently there are 3 Gulf War directed VA RFAs which include more than 80% of the recommended research topics received from the RACGWVI. The next set of RFAs will have 2 new RFAs specifically targeted at Pilot Projects.
 - b. Background for the VA proposed strategic plan
 - 1. VA Intramural Research Program
 - 2. Current VA R&D funding mechanisms
 - c. Strategic Plan Discussion
 - 1. Overall goal: "Improve the health and well-being of Gulf War I Veterans"
 - 2. High Level Goals presented for discussion (original draft version):
 - i. Identify and test new symptomatic treatments for ill Gulf War Veterans
 - ii. Identify therapeutic targets for development of new treatments for ill Gulf War Veterans

- (iia) Identify plausible hypotheses on the underlying causes and related pathways that might account for persistent symptoms using a systems approach
 - iii. Establish new case definition(s)
 - iv. Identify biomarkers/diagnostics for ill Gulf War Veterans
 - v. Improve coordination and communication with partners
 - 3. Dr. Grosser suggested adding a goal related to improving the progress across the clinical/transitional divide
 - 4. COL. Peters from the VA Chief of Staff Office wants to see sustainability of the plan over the next 3 years with accountability included
 - 5. Mr. Hardie suggested looking into the root cause behind the Gulf War Illness, looking more into exposure data.
 - 6. Dr. Buja pointed out that the plan needs to be linked to ongoing programs and then a gap analysis to determine priority areas. There was also discussion about not having priority areas assigned.
 - 7. The entity in-charge of the Gulf War Strategic Plan will be the new position reporting to Dr. Jaeger, Acting Director for Deployment Health.
- 8) Presentation by Dr. White
- a. Based on RACGWVI recommendations and discussions in how an integrated comprehensive program of research could be carried out. Dr. White said that it reflects RACGWVI thinking.
 - b. Presented the structure for a new "Comprehensive Gulf War Illness Research Program"
 - c. Discussion following Dr. White's presentation:
 - 1. Dr. Buja mentioned that the proposal was more of a national center which takes time and funding. The organization needs to focus on areas that can be light and changing as needed.
 - 2. Dr. O'Callaghan added that that the presentation highlighted the progress that has been made in understanding the illnesses affecting Gulf War Veterans and the ensuing discussion confirmed this view.
 - 3. Dr. White noted that she had previously submitted a center-based application for Gulf War research to the VA Cooperative Studies Program. Dr. Jaeger asked whether she would submit that same proposal today and the response was that, in light of the progress made since that time, she would not. This is because there has been considerable progress over the last 5 years in our understanding of GWVI through VA and other research.
 - 4. Dr. Kupersmith pointed out that the group needs an organized focus and should look into using a variety of existing mechanisms, including CSP.
 - 5. Dr. White indicated that there needs to be strong leadership, a strong plan, continual communication and strong research.
 - 6. Dr. Wenzel highlighted the need to keep the organization and structure separate and above the strategic plan.

7. The Steering Committee decided that the strategic plan should contain the following elements:
 - i. Establish new case definition(s)
 - ii. Identify plausible hypotheses on the underlying causes and related pathways that might account for persistent symptoms using a systems approach
 - iii. Identify and test new symptomatic treatments for ill Gulf War Veterans
 - iv. Identify biomarkers/diagnostics for ill Gulf War Veterans
 - v. Identify therapeutic targets for development of new treatments for ill Gulf War Veterans
 - vi. Continue and improve coordination/communication with partners
 - vii. Strategy to cross the translational divide

ACTION ITEMS:

- ORD Central Office will make revisions to the strategic plan and send it back out to the GWSC for review
- Schedule a phone call to further discuss the strategic plan
- GWSC was asked to prepare a 2 paragraph summary

Draft Strategic Plan (3-Year) for VA Gulf War Research Program

1. Identify/test new symptomatic treatments for ill Gulf War Veterans
2. Identify therapeutic targets for development of new treatments for ill Gulf War Veterans
 - a. Identify plausible hypotheses on the underlying causes and related pathways that might account for persistent symptoms
 1. Systems biology
 - a) Genomics
 - b) Proteomics
 - c) Metabolomics
 - d) Animal models
3. Establish new case definition(s)
4. Identify biomarkers/diagnostics for ill Gulf War Veterans
 - a. State-of-the-art Neuroimaging
 - b. Genomics
 - c. Proteomics
 - d. Metabolomics
5. Improve coordination and communication with partners
 - a. VA Office of Public Health and Environmental Hazards (OPEIH)
 - b. Congressionally Directed Medical Research Program (CDMRP), Gulf War Illness Research Program